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EXAMINER

KETTER, JAMES S

ART UNIT

PAPER NUMBER

1636

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12

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Applicati n No.

09/695,293

Applicant(s)

BERNSTEIN ET AL.

Examiner

James S. Ketter

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-- The MAILING DATE of this communication appears n the cover sheet with the c rrespond nce address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 25 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☐ Claim(s) \_\_\_\_\_ is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-34 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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The previous Office Action was also a restriction requirement, to which Applicants responded on 25 July 2002. However, it is noted that the Group which was elected, Group XLII, and also all other members of Supergrouping 2 (Groups XXVII-LII) were set forth as including claims 14 and 15. However, this was a typographic error carried over from the text of Supergrouping 1. Clearly, claims 14 and 15 are not drawn to amino acid sequences. Any inconvenience caused to Applicants is regretted.

**Applicants are not bound by the election filed 25 July 2002.**

(The corrected restriction requirement is set forth henceforth.)

The restriction Groups, designated with Roman numerals, have been set forth in 9 supergroupings, as the number of Groups is very large, and the Groups are of parallel structure in each supergrouping. The size of the Office Action required to set forth each Group separately would be prohibitively large.

**Applicants must elect a single restriction Group, not a supergrouping.**

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Supergrouping 1:

I-XXVI. Claims 1-3, 6 and 8-15, drawn to nucleic acids corresponding to SEQ ID NOS:1-26, respectively, and vectors, cells and pharmaceutical compositions comprising them, classified in class 435, subclasses 320.1 and 252.33.

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Supergrouping 2:

XXVII-LII. Claims 4, 5, 12 and 13, drawn to amino acid sequences corresponding to SEQ ID NOS:27-52, respectively, and pharmaceutical compositions comprising them classified in class 530, subclass 350.

Supergrouping 3:

LIII-LXXVIII. Claims 7, 14 and 15, drawn to antibodies having specificity for one of the amino acid sequences or SEQ ID NOS: 26-52, respectively, and pharmaceutical compositions comprising them, classified in class 530, subclass 387.1.

Supergrouping 4:

LXXIX-CIV. Claims 16-23, drawn to nucleic acid detection methods employing the nucleic acid of one of SEQ ID NOS:1-26, respectively, classified in class 435, subclass 6.

Supergrouping 5:

CV-CXXX. Claims 24-26, drawn to an assay for the effect of a compound on one of the amino acid sequences of SEQ ID NOS:27-52, respectively, classified in class 435, subclass 4.

Supergrouping 6:

CXXXI-CLVI. Claim 27, drawn to an activator of one of the amino acid sequences of SEQ ID NOS:27-52, unclassifiable.

Supergrouping 7:

CLVII-CLXXXII. Claim 28, drawn to a deactivator of one of the amino acid sequences of SEQ ID NOS:27-52, unclassifiable.

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Supergrouping 8:

CLXXXIII-CCVIII. Claims 29-32, drawn to amino acid sequence detection methods employing an antibody specific for one of the amino acid sequence of one of SEQ ID NOS:27-52, classified in class 435, subclass 7.1.

Supergrouping 9:

CCIX-CCXXXIV. Claims 33 and 34, drawn to an antibody detection method employing one of the amino acid sequences of SEQ ID NOS: 27-52, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions of supergroupings 1, 2, 3, 6 and 7 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are chemically distinct entities capable of supporting separate patents.

Inventions of supergroupings 1 and 4 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid may be expressed recombinantly to produce the corresponding polypeptides.

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Inventions of supergroupings 1 and 5 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to unrelated products, i.e., the method is a method of using a different product.

Inventions of supergroupings 1 and 8 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to unrelated products, i.e., the method is a method of using a different product.

Inventions of supergroupings 1 and 9 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to unrelated products, i.e., the method is a method of using a different product.

Inventions of supergroupings 2 and 4 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to unrelated products, i.e., the method is a method of using a different product.

Inventions of supergroupings 2 and 5 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the

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process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the amino acid sequences may be used to raise antibodies.

Inventions of supergroupings 2 and 8 are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product (the amino acid sequence) can be made by recombinant methods, or by direct chemical synthesis.

Inventions of supergroupings 2 and 9 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product, the amino acid sequence, can be used as an antigen to raise antibodies. The method of supergrouping 9 is a method of detecting antibodies that already exist, which is a distinct method.

Inventions of supergroupings 3 and 4 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to unrelated products, i.e., the method is a method of using a different product.

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Inventions of supergroupings 3 and 5 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to unrelated products, i.e., the method is a method of using a different product.

Inventions of supergroupings 3 and 8 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product, antibodies as recited, can be used in an affinity purification method, which is a distinct method from a detection method.

Inventions of supergroupings 9 and 3 are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the antibodies may be made by recombinant methods not involving a detection method step.

Inventions of supergroupings 4 and 5 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods which have different purposes and method steps, and which use different products.



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Inventions of supergroupings 6 and 5 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method can be used to identify deactivators of the amino acid sequence.

Inventions of supergroupings 7 and 5 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method can be used to identify activators of the amino acid sequence.

Inventions of supergroupings 5 and 8 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods which have different purposes and method steps, and which use different products.

Inventions of supergroupings 5 and 9 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods which have different purposes and method steps, and which use different products.

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Inventions of supergroupings 6 and 8 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a product and a method of using a different product.

Inventions of supergroupings 6 and 9 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a product and a method of using a different product.

Inventions of supergroupings 7 and 8 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a product and a method of using a different product.

Inventions of supergroupings 7 and 9 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a product and a method of using a different product.

Inventions of supergroupings 8 and 9 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of

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operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to different purposes, employing different method steps and different starting materials.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Certain papers related to this application may be submitted directly to the Examiner by facsimile transmission at (703) 746-5155. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94

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(December 28, 1993)(see 37 CFR ' 1.6(d)). To send the facsimile to the Art Unit instead, the Art Unit 1636 Fax number is (703) 305-7939. NOTE: If Applicant does submit a paper by fax to this number, the Examiner must be notified promptly, to ensure matching of the faxed paper to the application file, and the original signed copy should be retained by Applicant or Applicant's representative. (703) 308-4242 or (703) 305-3014 may be used without notification of the Examiner, with such faxed papers being handled in the manner of mailed responses. Applicant is encouraged to use the latter two fax numbers unless immediate action by the Examiner is required, e.g., during discussions of claim language for allowable subject matter. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the Examiner with respect to the examination on the merits should be directed to James Ketter whose telephone number is (703) 308-1169. The Examiner normally can be reached on M-F (9:00-6:30), with alternate Fridays off.

Questions regarding formalities and processing of the case should be directed to Zeta Adams, whose telephone number is (703) 305-3291.

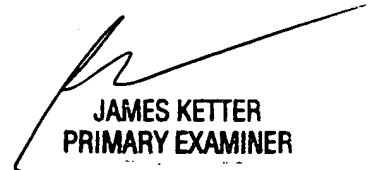
If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Remy Yucel, can be reached at (703) 305-1998.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Jsk

October 1, 2002



**JAMES KETTER**  
**PRIMARY EXAMINER**